UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

MARY J. BLOCK,

Plaintiff,

v.

WOO YOUNG MEDICAL CO. LTD., *a Hong Kong company*,

Defendant.

Civil No. 09-1332 (JRT/JJK)

MEMORANDUM OPINION AND ORDER

Yvonne M. Flaherty, **LOCKRIDGE GRINDAL NAUEN PLLP**, 100 Washington Avenue South, Suite 2200, Minneapolis, MN 55401-2179; and Thomas B. Powers, **WILLIAMS LOVE O'LEARY & POWERS, PC**, 12725 Southwest Millikan Way, Suite 300, Beaverton, OR 97005, for plaintiff.

Charles H. Cole, **SCHUYLER, ROCHE & CRISHAM, PC**, 130 East Randolph Street, Suite 3800, Chicago, IL 60601, and Stephen P. Laitinen, **LARSON KING, LLP**, 30 East Seventh Street, Suite 2800, St. Paul, MN 55101-4922, for defendant.

Plaintiff Mary J. Block brings this action against Woo Young Medical Co. Ltd. ("Woo Young"), alleging that a Woo Young pain pump that was inserted into the intra-articular space of her shoulder joint following surgery caused serious cartilage damage. Block brings a negligence claim against Woo Young under North Carolina law. Woo Young has moved for summary judgment and to exclude four of Block's experts. For the reasons explained below, the Court will deny Woo Young's motions.

BACKGROUND

I. SURGERY AND ITS ALLEGED RESULTS

On June 20, 2003, Block underwent arthroscopic shoulder surgery. (Am. Compl. ¶ 5, Dec. 24, 2010, Docket No. 173.) After Block's surgery, her surgeon, Dr. Kevin Speer, provided her with a Woo Young Accufuser pain pump that administered bupivacaine (also known as marcaine). (*See* Ex. 1 (Dep. of Kevin Speer 22), Dec. 28, 2012, Docket No. 290.) He placed the pump in the intra-articular space of Block's shoulder. (*See id.* 24.)

Block claims that she developed a degenerative joint disease called chondrolysis in her glenohumeral joint (i.e., shoulder joint), after the surgery. (Am. Compl. ¶¶ 5, 20.) Chondrolysis is the complete or nearly complete loss of cartilage in the joint, an irreversible and painful condition. (*Id.* ¶ 20.)

II. THE ACCUFUSER

Woo Young's Accufuser is a portable pain pump, a delivery mechanism for the continuous flow of medication. (*See* Def. Mem. in Support, Ex. 2, August 26, 2012, Docket No. 265.) In 2000, the Accufuser received 510(k) clearance[1] from the Food and Drug Administration ("FDA") to market pain pumps "for general infusion use[,]" including intravenous, percutaneous, subcutaneous, intra-arterial and epidural use and use

[1] "Premarket notification," also referred to by its section number, 510(k), is a process that allows manufacturers to market new devices on the basis that a "substantially equivalent" device is already on the market. *See Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574-75 (6th Cir. 2012). The alternative is a more rigorous process called "premarket approval" that involves detailed analysis of a device's safety. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-78 (1996).

in the intraoperative (soft tissue/body cavity) site. (*Id.*) The general approved uses for the pump included pain management for pre-operative, perioperative, and postoperative surgery. (*Id.*)

The FDA did not provide Woo Young with 510(k) clearance to market pain pumps for intra-articular use in connection with orthopedic, as opposed to general, surgeries. There is no indication in the record that Woo Young requested this specific clearance. However, the FDA had denied other companies' requests to receive 510(k) clearance to market pain pumps for such orthopedic indications.

III. DR. SPEER

Dr. Speer began to use pain pumps for postoperative pain relief after consulting with orthopedic surgeons and his anesthesiology colleagues. (Speer Dep. 19-20, 27.) Dr. Speer testified that he learned about this use for pain pumps from "orthopedic surgeons collaborating and talking about shared patient experiences and trying to expound on how they can do things better and what works and what doesn't." (*Id.* 20.) He also stated that he inquired about his colleagues' experiences with pain pumps "over time in different settings." (*Id.*)

Dr. Speer recalls speaking to sales representatives regarding pain pumps. (*Id.* 38.) These representatives told Dr. Speer about their experience and about whether doctors were using pain pumps. (*Id.*) The representatives directed Dr. Speer to doctors who were using the pain pumps so that he could target his inquiries to those doctors. (*Id.*)

Dr. Speer does not recall the names of the sales representatives with whom he spoke or the companies for which they worked. (*Id.*)

Dr. Speer did not perform independent research on pain pumps before using them on his patients, beyond his conversations with other doctors. (*Id.* 21.) Dr. Speer believed that his use of the pain pumps was approved by the FDA, based on talking to his colleagues, but he did not conduct any independent assessments of FDA clearances for the pumps. (*Id.* 26-27.) Dr. Speer stated, however, that he would take independent action to determine the FDA clearance for a device "if, after talking to my colleagues or in the other means of me getting the information that I seek, I f[ound] it to be inadequate or incomplete." (*Id.* 25.)

Dr. Speer has no recollection of the brand of pain pump that he used during Block's surgery. (*Id.* 27.) He believes he always used the same brand of pump that was provided by the hospital. (*Id.* 27-28.) Dr. Speer testified that he did not pay attention to the packaging on the pump. (*Id.* 29-30.) He did not state explicitly if he read any labels on pain pumps, however. Dr. Speer also stated that he had never heard of an "orthopedic kit" for a pain pump. (*Id.* 37.)

Around 2002, Dr. Speer first became aware of a patient who had developed chondrolysis of the shoulder after arthroscopic surgery. (*Id.* 40.) He then saw the problem occur in other patients. (*Id.* 41.) It was not until years later that he became aware that the problem might be due to the use of pain pumps. (*Id.* 41-42.) Dr. Speer still has not formed an opinion on what caused Block's chondrolysis. (*Id.* 43-44.) Furthermore, in his opinion, any reports of a suggested association between the use of

bupivacaine in the intra-articular space through pain pumps and chondrolysis did not arise until 2006, 2007, or 2008. (*Id.* 46.)

Dr. Speer's deposition is silent on the question of whether he would have heeded warnings concerning risks of cartilage damage associated with intra-articular pain pump use, from sales representatives or others, although it is clear that he sought information about the use of the pumps.

By 2006, 2007, or 2008 – or possibly sometime prior to those years – Dr. Speer had stopped using pain pumps in the shoulder joint. (*Id.*) Woo Young stated at oral argument that Dr. Speer stopped using pain pumps after he became aware of a potential link between chondrolysis and the intra-articular use of the pumps.

IV. CAUSES OF CHONDROLYSIS

The parties present conflicting views on the causes of chondrolysis. Woo Young claims that physicians could not explain exactly how or why chondrolysis occurred at the time of Block's surgery and that physicians still cannot do so today. (*See, e.g.*, Def. Mem. in Supp., Ex. 3 at 3.) Block disagrees and argues that the use of pain pumps to deliver intra-articular medications such as bupivacaine is cytotoxic to chondrocytes and is the primary cause of chondrolysis in certain patients. (Decl. of Thomas B. Powers, Ex. 6 at 3, Oct. 1, 2012, Docket No. 280.) Block points to medical literature, which, according to her experts, shows that cartilage cells are fragile and susceptible to damage when exposed to a variety of foreign substances. Block argues that a competent review of the

medical literature existing at the time of Block's surgery would have revealed the potential risks posed by using the pump near cartilage.[2]

V. OFF-LABEL MARKETING

The parties also dispute whether Woo Young engaged in off-label marketing and whether this marketing had any effect on Dr. Speer. Block points out that, in 2002, Woo Young entered into an exclusive distributor agreement with McKinley Infuser, LLC, for McKinley to sell Woo Young's products as part of a "pain kit for orthopedic surgery." (Powers Decl., Ex. 1 (Dep. of Woo Young Medical at 56-57), Ex. 2.) According to Block, this evidence shows that Woo Young marketed its product for orthopedic use.[3]

VI. TESTING OF PAIN PUMP

Woo Young knew that its pain pumps would be used to infuse medication into patients' bodies. (Powers Decl., Ex. 1 at 31.) Woo Young admits that it did not test the pain pump for the use of anesthetics that would be infused into the body through the pain pump. (*Id.* at 30.) It also did not request that any other company conduct such testing. (*Id.* at 32.) It also appears that Woo Young did not conduct a review of the medical literature related to this topic. (*Id.* at 29-30.)

[2] Block's arguments are supported by expert testimony that the Court will discuss in more detail below.

[3] Woo Young argues that there is no evidence that an orthopedic pain kit was ever sold on or before June 20, 2003. Also, Woo Young claims that there is no evidence that the Accufuser was, in fact, sold as part of an orthopedic pain kit or that such a kit was sold to Dr. Speer or to anyone at the hospital where Block's surgery was performed.

SUMMARY JUDGMENT

I. STANDARD OF REVIEW

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party can demonstrate that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could lead a reasonable jury to return a verdict for either party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences that can be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

II. NEGLIGENCE

Block's only remaining claim against Woo Young is a negligence claim.[4] She has narrowed this negligence claim to an allegation that Woo Young negligently failed to warn Dr. Speer about the possibility that Block could suffer cartilage damage if a pain pump was used to continuously infuse anesthetics into her intra-articular joint space.[5] The parties agree, for the purposes of this motion, that North Carolina law applies. Thus, the Court must determine if Woo Young is entitled to summary judgment on Block's

[4] Block concedes that Count 1 of her complaint should be dismissed. (Pl.'s Resp. in Opp. to Def.'s Mot. for Summ. J. at 6, Oct. 1, 2012, Docket No. 279.)

[5] It appears that both parties agree that North Carolina adheres to the learned intermediary doctrine. *See, e.g., Baraukas v. Danek Med., Inc.*, No. 6:97CV00613, 2000 WL 223508, at *4 (M.D.N.C. Jan. 13, 2000)).

failure to warn claim under North Carolina law. The Court will address each of Woo Young's arguments for summary judgment in turn.

A. Sale for Orthopedic Use

First, Woo Young claims that it cannot be held liable for the failure to warn because there is no evidence that it ever sold its pumps to orthopedic surgeons to be used near cartilage. Under North Carolina law, a manufacturer is not liable if its product is altered or modified after it leaves the manufacturer and the alteration or modification is the proximate cause of the plaintiff's injuries. N.C. Gen Stat. § 99B-3(a); *Edmondson v. Macclesfield L-P Gas Co.*, 642 S.E.2d 265, 272 (N.C. Ct. App. 2007). Alteration or modification includes "changes in the design, formula, function, or use of the product from that originally intended by the manufacturer." N.C. Gen Stat § 99B-3(b). A modification or alteration that is "'contrary to the instructions of the manufacturer and done without its express consent'" bars recovery from the manufacturer. *Edmondson*, 642 S.E.2d at 272 (quoting *Rich v. Shaw*, 391 S.E.2d 220, 223 (N.C. Ct. App. 1990)). A manufacturer can be held liable, however, if "the alteration or modification was made with the express consent" of the manufacturer. N.C. Gen. Stat. § 99B-3(a)(2).

The Court finds that the Accufuser was not necessarily altered or modified after leaving Woo Young's control and that there is a genuine issue of material fact regarding whether Woo Young can be held liable for failing to warn of risks associated with the orthopedic use of its product. There is evidence that Woo Young in fact promoted this use and expressly consented to the Accufuser's orthopedic, off-label use. Specifically,

Block has offered evidence that Woo Young consented to its distributor partner McKinley's efforts to sell the Accufuser pain pump to orthopedic surgeons as part of an "Orthopedic Kit" prior to the date of Block's surgery. Thus, there is a question of material fact regarding whether orthopedic use was the intended use of the pain pump or whether Woo Young consented to such use.

B. Dr. Speer and Causation

Woo Young also appears to argue that it cannot be held liable for Dr. Speer's use of the pain pump because there is no evidence of a causal link between Woo Young's behavior and Dr. Speer's use of the pain pump. In order to prevail on a failure to warn claim, a plaintiff must establish that an adequate warning would have prevented his or her injuries. *See Holley v. Burroughs Wellcome Co.*, 330 S.E.2d 228, 233 (N.C. Ct. App. 1985). "Under North Carolina law, evidence that a product user would have altered her conduct when presented with an adequate warning has been held to be sufficient to present a factual issue for the jury." *See Richardson v. Gen. Motors Corp.*, 223 F. Supp. 2d 753, 757 (M.D.N.C. 2002).

Here, the Court concludes that there is a genuine issue of material fact regarding whether an adequate warning would have changed Dr. Speer's behavior. Dr. Speer actively sought information about the use and safety of pain pumps, over time and in different settings. Dr. Speer testified that he believed the FDA had approved his use of pain pumps and that he would have conducted additional research if he felt he had received incomplete information about the appropriate use of the pumps. Dr. Speer never

testified that he did not read labels or Dear Doctor letters, nor did he testify that he would have been unresponsive to warnings from sales representatives, doctors, or others about the use of the pain pumps. A reasonable jury could therefore find that if Woo Young had warned individuals in the medical community about the orthopedic use of its pain pumps, Dr. Speer would have been likely to learn about the risks associated with pain pumps and altered his behavior. *See, e.g.*, *Bonander v. Breg, Inc.*, Civ. No. 09-2795, 2012 WL 4128386, at *4 (D. Minn. Sept. 18, 2012) (finding genuine issue of material fact where doctor may have heeded Dear Doctor letters, communications from sales representatives, or other warnings). Accordingly, the Court will not grant summary judgment on the ground that an adequate warning would not have altered Dr. Speer's behavior.

C. Foreseeability

Woo Young next argues that it cannot be held liable for the failure to warn because Block's injuries were not foreseeable. There are three main elements that Block must prove to succeed on her failure to warn claim: (1) that Woo Young acted unreasonably by failing to provide a warning or instruction; (2) that Woo Young's failure to provide a warning or instruction was the proximate cause of her harm; and (3) that when the pain pump left Woo Young's control without an adequate warning or instruction, it created an unreasonably dangerous condition that Woo Young knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a

reasonably foreseeable claimant.[6] N.C. Gen. Stat § 99B-5; *see also Evans v. Evans*, 569 S.E.2d 303, 311 (N.C. Ct. App. 2002) (concurring opinion). Woo Young claims that these elements are not met because it did not know, nor in the exercise of ordinary care should it have known, that its pain pumps posed a risk of chondrolysis.[7]

As a preliminary matter, the Court notes that courts across the country have confronted the issue of whether the risks associated with intra-articular pain pump use were foreseeable with inconsistent results. *See, e.g.*, *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 577 (6th Cir. 2012) (affirming grant of summary judgment); *Krumpelbeck v. Breg, Inc.*, No. 11-3762, 2012 WL 3241587, at *8 (6th Cir. Aug. 10, 2012) (reversing, in part, grant of summary judgment); *Phillippi v. Stryker Corp.*, 2:08-CV-02445, 2010 WL 2650596, at *3 (E.D. Cal. July 1, 2010) (granting summary judgment); *Hackett v. Breg, Inc.*, Civ. No. 10CV1437, 2011 WL 4550186, at *4 (D. Colo. Oct. 3, 2011) (denying summary judgment); *Kildow v. Breg, Inc.*, 796 F. Supp. 2d 1295, 1299-300 (D. Or. 2011) (denying summary judgment). In those cases that reached a jury, multiple juries have

[6] As an alternative to this third element, liability can also exist if "[a]fter the product left the control of the manufacturer or seller, the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances." N.C. Gen. Stat § 99B-5(a)(2).

[7] Woo Young correctly notes that foreseeability has been discussed by North Carolina courts both in terms of the duty owed and in terms of proximate cause. *See Winters v. Lee*, 446 S.E.2d 123, 124 (N.C. Ct. App. 1994) (cataloguing cases). The Court need not determine whether, under North Carolina law, foreseeability is properly considered under the duty inquiry or the proximate cause inquiry. The Court's finding that genuine issues of material fact remain as to foreseeability renders summary judgment inappropriate whether it relates to duty or proximate cause.

found that the risks were foreseeable. *See, e.g.*, Final Judgment, *Hackett v. Breg, Inc.*, Civ. No. 10-1437 (D. Colo. Nov. 22, 2011); *Beale v. I-Flow Corp.*, No. 0801-01554 (Ore. Cir. Ct., Multnomah Cnty. Dist. Jan. 22, 2010).

Under North Carolina law, "[t]he duty of ordinary care is no more than a duty to act reasonably. The duty does not require perfect prescience, but instead extends only to causes of injury that were reasonably foreseeable and avoidable through the exercise of due care." *Fussell v. N.C. Farm Bureau Mut. Ins. Co.*, 695 S.E.2d 437, 440 (N.C. 2010). Thus, it is sufficient to demonstrate a breach of the duty of ordinary care "if by the exercise of reasonable care the defendant might have foreseen that some injury would result from his conduct or that consequences of a generally injurious nature might have been expected." *Id.* (internal quotation marks omitted). The question of foreseeability is usually for the jury. *Id.*

Here, there appears to be no allegation that Woo Young actually knew of the risk to cartilage associated with intra-articular pain pump use. Thus, the question becomes whether, in the exercise of ordinary care, Woo Young should have known of the risk. To answer this question, the Court will first consider the nature of the risk that must have been foreseeable to Woo Young. Next, the Court will consider whether, under North Carolina law, there is a duty to test to determine the risks associated with a product. Finally, considering these first two factors, the Court will determine whether the risk alleged by Block was foreseeable in this case.

1. Nature of Risk

The Court must first determine exactly what "risk" must have been foreseeable in order for Woo Young to potentially be liable. "It is well settled that the test of foreseeability as an element of proximate cause does not require that defendant should have been able to foresee the injury in the precise form in which it actually occurred." *Hairston v. Alexander Tank and Equip. Co.*, 311 S.E.2d 559, 565 (N.C. 1984). Thus, Block need not establish that Woo Young should have known that intra-articular pain pump use could cause **chondrolysis** because the test is not whether the **precise nature** of the plaintiff's injury was foreseeable. Rather, the Court finds that if the evidence establishes that Woo Young should have known that intra-articular pain pump use posed a risk of cartilage damage, this could be sufficient to give rise to a duty to warn.[8] *See Mack v. Stryker Corp.*, 2012 WL 3599458, at *8 n.6 (D. Minn. Aug. 14, 2012); *Schoenborn v. Stryker Corp.*, 801 F. Supp. 2d 1098, 1102 (D. Or. 2011).

2. Duty to Test

Second, the Court will consider the extent of Woo Young's duty to test for potential risks associated with its pain pumps. Woo Young argues that it cannot be held

[8] "A defendant is not required to foresee events which are merely possible but only those which are reasonably foreseeable." *Hairston*, 311 S.E.2d at 565. "If the connection between negligence and the injury appears unnatural, unreasonable[,] and improbable in the light of common experience, the negligence, if deemed a cause of the injury at all, is to be considered remote rather than a proximate cause." *Williamson v. Liptzin*, 539 S.E.2d 313, 319 (N.C. Ct. App. 2000) (citing *Phelps v. Winston-Salem*, 157 S.E.2d 719, 723 (N.C. 1967)). As will be explained below, although a jury may find that the risk of cartilage damage posed by intra-articular pain pump use was "merely possible" or "improbable" in light of what Woo Young "should have known" at the time, the Court concludes that a jury could find otherwise.

liable for the failure to test the use of pain pumps distributing anesthetics in the intra-articular space because there is no duty to test recognized in failure to warn claims under North Carolina law. The parties have cited to no North Carolina cases directly on point and the Court has found none. The Court finds, however, that that the North Carolina Supreme Court would recognize that a manufacturer may have a duty to test that bears on what risks are foreseeable and require warnings. *See, e.g.*, *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1528 (D. Minn. 1989) ("The duty to test is a subpart of duties to design a product non-negligently, manufacture a product non-negligently, and provide adequate warnings of dangers associated with its use.").

The parties have cited to no cases that explicitly reject the existence of a duty to test in a failure to warn claim under North Carolina law.[9] North Carolina law has recognized a duty to test in the context of negligence claims relating to the design and manufacture of products, however. *See Nicholson v. Am. Safety Utility Corp.*, 476 S.E.2d 672, 676 (N.C. 1996). The North Carolina Supreme Court has also held that manufacturers must exercise due care to recognize whether a product poses "an

[9] *Nicholson v. American Safety Utility Corp.* held that "[a] manufacturer must use reasonable care in the design and manufacture of products, and this includes the duty to perform 'reasonable tests and inspections to discover latent hazards.'" 476 S.E.2d 672, 676 (N.C. 1996) (quoting *Cockerham v. Ward*, 262 S.E.2d 651, 654 (1980)). While this statement refers explicitly to only the design and manufacture of products, the court went on to hold that "[r]eview of the record in light of the foregoing principles reveals the existence of a genuine issue of material fact as to the alleged failure of defendants . . . to test and inspect the gloves properly and to convey adequate warning of potential deficiencies in the gloves." *Id.* at 676-77. The Court does not read *Nicholson* as clearly deciding whether there is a duty to test that is relevant to a failure to warn claim. *Cockerham* similarly explicitly recognizes a duty to test, but does not explicitly hold that it may have a connection with a failure to warn claim. *See* 262 S.E.2d at 654.

unreasonable risk of harm" and that "[i]n this connection, a manufacturer is under a duty . . . to make reasonable tests and inspections to discover latent hazards involved in the use of its products." *Cockerham v. Ward*, 262 S.E.2d 651, 654 (1980). Because North Carolina has recognized a duty to test in similar contexts, the Court finds that it is likely to do so in the context of a failure to warn claim, though it has not yet done so explicitly. The existence of a duty to pursue reasonable safety testing to determine the safety of a product is also consistent with the duty under North Carolina law to warn of risks that are not only known but also those which should have been known. *See* N.C. Gen. Stat. § 99B-5. The Court thus finds that North Carolina is likely to recognize a duty to test in connection with a failure to warn claim.[10]

3. Foreseeability in this Case

Turning to the evidence presented in this case, the Court finds that there was sufficient evidence of a risk of cartilage damage to alert Woo Young to the possible need for warnings and to the potential need for more testing to determine the safety of its pain pump. Block relies largely on her experts' opinions that the medical literature existing prior to her surgery was sufficient to put a manufacturer on notice that continuously

[10] The Court also notes that Minnesota law, which is similar to North Carolina law, recognizes a duty to test. Minnesota law, like North Carolina law, states that "[a] manufacturer has a duty to warn of dangers where it knew or should have known of the risk or hazard involved." *See Harmon Contract Glazing, Inc. v. Libby-Owens-Ford Co.*, 493 N.W.2d 146, 151 (Minn. Ct. App. 1992). Under this standard, Minnesota courts have held that "[a] manufacturer is held to the skill of an expert in its particular field of endeavor, and is obligated to keep informed of scientific knowledge and discoveries concerning that field[,]" *Karjala v. Johns-Manville Prods. Corp.*, 523 F.2d 155, 159 (8th Cir. 1975), and that manufacturers' duty to test the safety of their products can bear on the warnings that are required, *Willmar Poultry Co. v. Carus Chem. Co.*, 378 N.W.2d 830, 836 (Minn. Ct. App. 1985).

injecting anesthetic into the intra-articular joint space could cause serious cartilage damage. While it may be that no single article or study presented exactly this conclusion, Block's experts opine that a number of studies are relevant by analogy and would have presented clear red flags to Woo Young had Woo Young conducted a reasonable review of the literature in its field.[11] After considering the state of the literature and what was known generally about the anatomy of cartilage and joint spaces, Block's experts conclude that a manufacturer who conducted a reasonable literature review prior to the time of Block's surgery would have known that intra-articular pain pump use could cause serious cartilage damage.

Additionally, Block has presented evidence that Woo Young did not conduct or commission tests to determine the risks of post-operative continuous infusion of anesthetic into the intra-articular space. Not only did Woo Young allegedly not test the safety of this use, but Woo Young also allegedly marketed its products for this use, which could be relevant to the foreseeability of the harm that resulted.[12] Block has also presented evidence that FDA reviewers repeatedly denied the efforts of other companies

[11] More details about the conclusions of Block's experts are provided in the EXPERTS sections II-III *infra*.

[12] As Woo Young's expert, Dr. Jeffrey Swenson, opined, "The lack of prospective data proving the safety of prolonged local anesthetic infusion in the joint should have given [physicians] pause" and that "[b]efore using any drug, the physician should thoroughly understand its formulation, side effects, and risks." (Powers Decl., Ex. 23 at 4.) Thus, according to Woo Young's own expert, the safety of prolonged local anesthetic infusion in the joint was not adequately demonstrated in and after 2002. This lack of demonstrated safety could have, similar to physicians, given Woo Young pause and led to more testing.

to obtain 510(k) clearance to include use in the intra-articular space on pain pump labels.[13]

Considering all of the evidence in the light most favorable to Block, the Court finds that a genuine issue of material fact remains as to whether Woo Young should have known of the risks of intra-articular pain pump use. In light of the evidence Block has presented regarding the scientific literature, the lack of testing, the lack of FDA 510(k) clearance, and Woo Young's marketing, a jury could reasonably find by a preponderance of the evidence that Woo Young should have known the risks of intra-articular pain pump use and had a duty to warn of these risks. *See* N.C. Gen. Stat § 99B-5. Therefore, the Court will deny Woo Young's motion for summary judgment.[14]

EXPERTS

Woo Young also brings a variety of motions to exclude experts. These motions include a motion to exclude Block's general causation experts, a motion to exclude the expert testimony of Dr. David Bailie (a general causation expert), a motion to exclude the

[13] Some courts have recognized that the simple denial of 510(k) clearance, without more, does not necessarily mean that a device is unsafe or that a manufacturer should know it poses certain risks. *See, e.g.*, *Rodriguez*, 680 F.3d at 574 ("The FDA's action means only that no other device on the market carried that indication for use. It does not mean that the pump was (or might potentially be) dangerous to use in the joint space."); *Forslund v. Stryker Corp.*, Civ. No. 09-2134, 2010 WL 3905854, at *4 n.5 (D. Minn. Sept. 30, 2010). But Block does not rely solely on the fact that the FDA denied 510(k) applications, but also relies on the other evidence outlined above to argue that there were red flags regarding the safety of pain pumps for use in the intra-articular space.

[14] For similar reasons, the Court rejects Woo Young's argument that Block, as a matter of law, cannot show that pain pumps can cause chondrolysis. The testimony of Block's experts, described below, support this alleged causal link.

expert testimony of Dr. Stephen Badylak (a general causation expert), a motion to exclude the expert testimony of Dr. Suzanne Parisian, and a motion to exclude the expert testimony of Maria Vargas and Larry Stokes. The Court will deny these motions, for the reasons described below.[15]

I. STANDARD OF REVIEW

Under Federal Rule of Evidence 702, governing the admissibility of expert testimony, expert testimony must satisfy three prerequisites to be admitted:

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires . . . .

Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001) (citations and internal quotation marks omitted). The district court has a "gate-keeping" obligation to make certain that all testimony admitted under Rule 702 satisfies these prerequisites and that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993).

> The inquiry as to the reliability and relevance of the testimony is a flexible one designed to 'make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom

[15] Although there initially appeared to be a dispute in this regard, the parties agreed at oral argument – correctly, in the Court's view – that federal law applies to these motions. *See, e.g., Two Rivers Bank & Trust v. Atanasova*, 686 F.3d 554, 563 (8th Cir. 2012) ("The Federal Rules of Evidence, not state law, provide the standards for evidentiary issues in a diversity action.").

> the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'

Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 757 (8th Cir. 2006) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). The proponent of the expert testimony has the burden of establishing by a preponderance of the evidence that the expert is qualified, that his or her methodology is scientifically valid, and that "the reasoning or methodology in question is applied properly to the facts in issue." *Id.* at 757-58.

An expert opinion is inadmissible if its sole basis is studies that do not provide a sufficient foundation for the opinion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145 (1997). However, courts must look to the totality of evidence in determining whether an expert's opinion is relevant and reliable, looking to the overall sufficiency of the underlying facts and data and the reliability of the methods used. *See, e.g., United States v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007). When studies form a basis for an expert's opinion, then, the Court must determine if there is an adequate basis for the experts' opinion and whether there is "too great an analytical gap between the data and the opinion proffered." *See Joiner*, 522 U.S. at 146.

In addition, "[c]ourts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *Id.* at 758; *see also Kumho*, 526 U.S. at 152 ("[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."). "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must

such testimony be excluded." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (quoting *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996)). "*Daubert* does not require proof with certainty." *Sorenson v. Shaklee Corp.*, 31 F.3d 638, 650 (8th Cir. 1994). Rather, it requires that expert testimony be relevant and reliable. *Id.*

II. MOTIONS TO EXCLUDE CAUSATION EXPERTS

Woo Young first challenges Block's general causation experts, stating that their reports and conclusions fail to satisfy the standards of scientific reliability under Federal Rule of Evidence 702 and *Daubert*. These experts are David Bailie, M.D., and Stephen F. Badylak, DVM.

A. Experience and Opinions of Drs. Badylak and Bailie

Dr. Badylak has training as a medical doctor, clinical pathologist, anatomic pathologist, and veterinarian. (Ex. 1 (Report of Dr. Badylak at 2), Aug. 16, 2012, Docket No. 267.) He is a full-time professor at the University of Pittsburgh in the McGowan Institute for Regenerative Medicine. (*Id.*) He has experience in tissue engineering and regenerative medicine, which is the study of diseased or missing tissues and the development of strategies and methodologies for the reconstruction and regeneration of such tissues. (*Id.*) He holds more than fifty United States patents in the field of regenerative medicine, including patents directed toward technology to treat shoulder pathology in patients with rotator cuff injury, and he has served on advisory committees for the Food and Drug Administration. (*Id.*)

Dr. Badylak opines that: (1) "[t]he use of pain pumps to deliver intra-articular medications such as marcaine alone, marcaine with epinephrine, or other local anesthetics that have been shown to be cytotoxic to chondrocytes is the primary cause of chondrolysis in these patients" and (2) "[t]here is no reason to suspect other causes of chondrolysis in cases in which continuous intra-articular infusion of marcaine has been used." (*Id.* at 3, 52.) In addition, he claims that (3) "[t]he misrepresentation of FDA sanctioned use of intra-articular application of pain pumps by industry representatives is clearly and causally related to chondrolysis caused by continuous intra-articular infusion of marcaine at either 0.25% or 0.50% with or without associated use of epinephrine." (*Id.* at 52.) Dr. Badylak's opinions are based upon his survey of medical and scientific literature and on his "education, training, clinical and research experience and general references within [his] field of research[.]" (*Id.* at 51.)

Dr. Bailie is a board certified orthopedic surgeon whose practice is focused on sports medicine and reconstructive surgery of the knee and shoulder. (Ex. 1 (Expert Report of Dr. Bailie at 2), Aug. 16, 2012, Docket No. 268.) Among other experience, he has consulted or is currently a consultant for several sports medicine and orthopedic device companies, including one that previously distributed continuous infusion pain pumps for orthopedic surgery. (*Id.* at 3.)

Dr. Bailie opines that "to a reasonable degree of medical probability . . . 'PAGCL' [Post-Arthroscopic Glenohumeral Chondrolysis] is strongly linked and caused by continuous infusion of local anesthetics via pain pumps." (*Id.* at 14.) He bases this opinion on various factors, including a rapid rise in documented cases of chondrolysis

associated with pain pump uses, in vitro and animal data that support significant chondrotoxicity of local anesthetics in a time/dose dependent manner, his review of the available literature, and his personal experience with chondrolysis and anthroscopic shoulder surgery. (*Id.*) Dr. Bailie reports that he never heard of a case of chondrolysis in any of his patients before he used pain pumps intra-articularly to continuously deliver a local anesthetic. (*Id.* at 4.) After he began using pain pumps in this manner on patients, he discovered that some of these patients developed chondrolysis in the shoulder. (*Id.* at 5-7.) He has not seen any cases of chondrolysis in his patient population since discontinuing the use of pumps to infuse anesthetics into the joint. (*Id.* at 4.)

B. General Motion to Exclude

In its general motion to exclude Drs. Badylak and Bailie, Woo Young argues that the scientific community is uncertain about the causes of chondrolysis. Woo Young further maintains that, because the causation experts did not conduct their own research, they must rely on other studies and that those studies do not support their conclusions.

With respect to the reliability of these experts' testimony, the Court notes that a difference of opinion regarding an expert's conclusions is usually a topic for cross-examination and competing testimony, not a reason to exclude testimony. *See Daubert*, 509 U.S. at 595. However, there are limits to this principle. Expert opinions drawn from existing data are inadmissible if "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 552 U.S. at 146.

The Court finds that there is sufficient support for Drs. Badylak and Bailie's opinions at this stage.[16] It is a commonly accepted methodology to examine literature in one's field and draw conclusions from it, and expert opinions may be based on professional studies as well as personal experiences. *See id.* ("Trained experts commonly extrapolate from existing data."); *Marmo*, 457 F.3d at 757. Here, Drs. Badylak and Bailie have supported their opinions through professional studies as well as their relevant experience.

More specifically, although the sources of their opinions vary somewhat, Drs. Badylak and Bailie rely on clinical, animal, and in vitro studies, textbook references, clinical experience, and other sources of information that support a link between cartilage damage and the use of pain pumps to deliver certain medications into the intra-articular space. Block provides a thorough account of the literature that supports a link between cartilage damage and the intra-articular use of pain pumps, which the Court will not repeat in detail here. (Mem. in Opp. to Mot. to Exclude Expert Testimony at 9-39, Oct. 1, 2012, Docket No. 276.) The Court finds that the conclusions of Drs. Badylak and Bailie, which are drawn in part from the literature noted above, are sufficiently relevant and reliable to be helpful to the jury and meet *Daubert*'s requirements. *See Daubert*, 509 U.S. at 589. Thus, the jury may consider this evidence. *See Lauzon*, 270 F.3d at 686; *Bonner*, 259 F.3d at 929-30 (quoting *Hose*, 70 F.3d at 974).

[16] As the Court explained above, if the evidence establishes that Woo Young should have known that intra-articular pain pump use posed a risk of cartilage damage, it is sufficient to give rise to a duty to warn. Therefore, the experts' opinions regarding the literature are relevant and satisfy *Daubert*'s "fit" requirement. *See Daubert*, 509 U.S. at 591.

C. Motion to Exclude Dr. Badylak

In its motion to exclude Dr. Badylak specifically, Woo Young argues that Dr. Badylak is not an orthopedic surgeon and that his experience is therefore insufficient to render the opinions he offers. The Court finds otherwise. Dr. Badylak is a medical doctor with knowledge, expertise, and training in cartilage. For example, he has authored more than 200 peer-reviewed articles on tissue engineering and regenerative medicine, and he has conducted research on various aspects of injuries to joints and limbs. The Court finds that he is qualified to assist the finder of fact on the areas on which he seeks to testify. *See Lauzon*, 270 F.3d at 686.

Woo Young further argues that Dr. Badylak cannot opine about the FDA process because there is no proof that he was aware of the FDA's knowledge regarding pain pumps being used in the intra-articular space and because he does not have knowledge about Woo Young's involvement with the FDA. Block responds that Dr. Badylak will not testify about the role of the FDA in the marketing and licensure of pain pumps, but rather that he will testify about the published medical literature and what it shows about the risk that pain pumps posed. The Court will allow Dr. Badylak to testify about what, in his opinion, a manufacturer would have known about the risk of pain pumps had it reviewed the literature because this issue is highly relevant to Woo Young's failure to warn. *See* N.C. Gen. Stat § 99B-5 (requiring manufacturer to act reasonably in providing warnings or instructions). If Dr. Badylak in fact attempts to testify about the role of the

FDA in the marketing and licensure of pain pumps, the Court will entertain an objection to such testimony at that time.[17]

D. Motion to Exclude Dr. Bailie

In its motion to exclude Dr. Bailie, Woo Young argues that Dr. Bailie's anticipated testimony is inadmissible because his opinions are not well-supported. Among other arguments,[18] Woo Young argues that Dr. Bailie's opinions contradict a recent peer reviewed article that he authored. In this article from 2009, Dr. Bailie stated that "the actual cause of even the reported cases [of chondrolysis] has not been confirmed, and the associations [between chondrolysis and the use of pain pumps to infuse anesthetics into the joint] are speculative at this juncture." (Ex. 6 at 3, Aug. 16, 2012, Docket No. 268.) The article also states, however, that further study on these associations is needed and that, until such studies were completed, the authors strongly advised against the use of large doses of local anesthetics in the intra-articular space. (*Id.* at 2.)

[17] Woo Young also argues that Dr. Badylak lacks sufficient facts or data to support his general causation opinion, that Dr. Badylak did not use reliable principles or methodologies and unreliably applied his principles and methodologies, that Dr. Badylak cannot draw conclusions not drawn by the articles he cites, and that Dr. Badylak has failed to account for other potential causes of chondrolysis. As stated above, the Court finds that Dr. Badylak's opinions are sufficiently supported and reliable.

[18] Specifically, Woo Young alleges that Dr. Bailie lacks sufficient facts or data to support his general causation opinion, did not use reliable principles or methodologies in rendering his expert opinions, and unreliably applied his principles and methodologies to the facts and data on which he relies. It specifically argues that Dr. Bailie's opinions are not supported by the scientific evidence provided in the articles he reviewed. As stated above, the Court finds sufficient support for Dr. Bailie's opinions through the literature and his clinical experience.

The Court will deny Woo Young's motion regarding Dr. Bailie. Dr. Bailie is an orthopedic surgeon with significant relevant experience, including experience as a consultant to medical device makers and experience participating in the design and development of shoulder replacement components. As noted above, the Court finds that Dr. Bailie's opinions are adequately supported by literature as well as his clinical experience. *See Marmo*, 457 F.3d at 757.

The Court also does not find that Dr. Bailie's opinions are inadmissible because of his 2009 article. Dr. Bailie explains in his expert report that, in his view, many more clinical and laboratory studies have been published and presented on the link between chondrolysis and the use of pain pumps to infuse anesthetics into the joint since this article's publication. (Report of Dr. Bailie at 7.) Furthermore, the 2009 article plainly presents concerns about the potential link between chondrolysis and the use of pain pumps to infuse anesthetics into the joint. To the extent that there might be any contradiction between Dr. Bailie's article and his current opinions, the Court finds that this is a proper subject for cross examination. *Bonner*, 259 F.3d at 929 ("'As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.'" (quoting *Hose*, 70 F.3d at 974)). Accordingly, the Court will deny Woo Young's motions regarding the causation experts.

III. MOTION TO EXCLUDE DR. PARISIAN

Woo Young next moves to exclude the testimony of Dr. Suzanne Parisian. Block identified her as an expert on general causation and FDA regulations and guidelines. Woo Young seeks to exclude her testimony on numerous grounds.

Block states that Dr. Parisian will testify regarding (1) the role, procedures and function of the FDA in overseeing medical device manufacturers; (2) the duties and responsibilities of defendants to obtain FDA clearance for their pain pumps in the United States for post-operative pain management and to market safe and effective devices; and (3) the duties and responsibilities of defendants to protect the public by monitoring device performance (including proper studies and following up on potential side effects) and communication of the risks attendant to the use of their devices.[19]

As a preliminary matter, the Court notes that the proposed testimony of Dr. Parisian has received varying treatment from the courts. *See, e.g.*, *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1351 (S.D. Fla. 2010) ("Plainly stated, Dr. Parisian is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding by the opinion constraints of Rule 702."); *but see, e.g.*, (Ex. 5 at 3-4, Oct. 1, 2012, Docket No. 275) (stating that Dr. Parisian was the "best behaved witness" and was "extremely helpful"). The Court has reviewed these opinions and, based on this review, does not find that Dr. Parisian is an uncontrollable or

[19] The Court notes that this motion in part repeats challenges to the medical literature that the Court has already addressed.

inappropriate witness. Instead, the Court will consider the merits of Woo Young's challenges to the substance of her testimony.

Dr. Parisian received her Medical Doctorate in 1978 and is board certified in anatomic and clinical pathology. (Decl. of Matthew Munson, Ex. 1 at 86, Oct. 2, 2012, Docket No. 282.) She also holds a Masters Degree in biology. (*Id.*) Among other relevant experience, Dr. Parisian has served as an FDA Medical Officer and later as the Chief Medical Officer in the FDA's Office of Device Evaluation. (*Id.* at 5.) In this position, she provided regulatory support to the FDA, health hazard and health risk assessments, safety alerts, reviews of adverse event reports and medical literature, and reviews of product labeling, promotions, advertising, and corporate records regarding compliance with the Food, Drug, and Cosmetic Act ("FDCA"). (*Id.*) In addition, she presided over 162 health risk assessments convened to advise the FDA on overall health risk issues for the public and made recommendations to the FDA regarding the subsequent regulatory actions that should be undertaken by the FDA, health care providers, users groups and manufacturers to help protect the public's welfare. (*Id.*) Although Dr. Parisian has now left the FDA, she continues to provide information to individuals, manufacturers, and organizations on the FDA's requirements, adverse event reporting, and the labeling, promotion and advertising of FDA-regulated products. (*Id.* at 7.)

Woo Young first argues that Dr. Parisian cannot testify about what Woo Young knew or what was knowable to Woo Young at particular periods in time. Specifically, Woo Young argues that Dr. Parisian cannot testify as to whether Woo Young knew that

other companies were not cleared by the FDA for orthopedic surgery indications or whether Woo Young should have known the potential risk to cartilage from infusions following orthopedic surgery. Block responds that Dr. Parisian will not express any opinions on the intent, motives, or state of mind of Woo Young. The Court finds that this issue is moot to the extent that Dr. Parisian might testify as to the intent, motives, or state of mind of Woo Young. However, the Court will not exclude testimony that is relevant to what Woo Young **should** have known. As stated above, the issue of what Woo Young should have known is relevant to Block's failure to warn claim. *See* N.C. Gen. Stat § 99B-5 (requiring manufacturer to act reasonably in providing warnings or instructions). The Court will thus allow Dr. Parisian to testify to the state of the medical literature, the state of FDA approval, and other information about which Woo Young should have been aware. The Court further finds that Dr. Parisian has sufficient expertise to offer this testimony as a medical doctor who formerly worked for the FDA. Any challenges to Dr. Parisian's expertise on these topics can be addressed on cross examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Similarly, Woo Young challenges Dr. Parisian's testimony relating to entities other than Woo Young, such as testimony about how other companies were not cleared by the FDA for orthopedic surgery indications. As stated above, the Court finds that this testimony could be relevant to what Woo Young **should** have known had it investigated the safety of pain pumps. It could also be relevant to whether Woo Young should have

conducted further testing about the safety of such pumps. If Dr. Parisian testifies to matters that are too unrelated to Woo Young for a jury to reasonably take them into account when assessing what Woo Young should have known, the Court will entertain objections to such testimony at trial.

Woo Young also argues that Dr. Parisian should not be allowed to testify about whether Woo Young had a defective design and did not follow good manufacturing practices, because Block's design defect claim will be dismissed. The Court will not allow any testimony at trial that solely relates to a design defect claim. The Court notes, however, that there may be some overlap in evidence that applies to a design defect and failure to warn claim because the specifics of a product's design may lead to the need for particular warnings. *See, e.g.*, *Kurns v. RR Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 (2012) ("A failure-to-warn claim alleges that the product itself is unlawfully dangerous unless accompanied by sufficient warnings or instructions."). If Dr. Parisian's testimony strays and addresses matters that are not relevant to a failure to warn claim, the Court will exclude such testimony.

The parties also dispute whether Dr. Parisian should be allowed to state her opinion as to whether Woo Young met or departed from industry standards of care as defined by FDA regulations. Block argues that, to decide whether Woo Young breached its duties of care, the jury will need to hear from a knowledgeable expert to explain the FDA's role in regulating medical devices, how those regulations apply to Woo Young, and whether Woo Young complied with FDA standards. Block also argues that Woo Young's liability hinges on the reasonableness of their interpretation of, and compliance

with, the applicable FDA standard of care. Woo Young counters that Dr. Parisian should not be allowed to testify on such topics.

The Court concludes that Dr. Parisian cannot testify regarding an FDA standard of care or standard of conduct, to the extent that such a term indicates compliance with applicable FDA regulations. Implied preemption bars state tort claims that "exist solely by virtue of . . . [Food, Drug, and Cosmetic Act ("FDCA")],. . . requirements" and include "the existence of . . . federal enactments [a]s a critical element[.]" *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 352-53 (2001). In other words, Block and Dr. Parisian cannot argue, or suggest, that Woo Young should face liability simply because it allegedly violated FDA laws or "standards." *See In re Medtronic*, 623 F.3d 1200, 1204 (8th Cir. 2010). Stating that Woo Young violated an FDA standard of care, or offering similar testimony, will not be permitted. Similarly, Dr. Parisian cannot testify that Woo Young is liable because it promoted its devices in manners inconsistent with the FDCA.

However, claims arising from a "manufacturer's alleged failure to use reasonable care[,] not solely from the violation of FDCA requirements," are not impliedly preempted because they are premised on "traditional state tort law which had predated the federal enactments in question[.]" *Buckman*, 531 U.S. at 352-53. Block and Dr. Parisian can therefore properly offer evidence that Woo Young failed to provide a warning of a foreseeable risk posed by a foreseeable use of their pain pump (*i.e.*, cartilage damage caused by post-operative continuous infusion of anesthetics into the intra-articular space). The fact that Woo Young allegedly marketed pain pumps for intra-articular use, particularly after the FDA denied a specific clearance for that use, is also relevant to

whether it should have known the risks associated with intra-articular use and whether it was foreseeable that surgeons would pursue intra-articular use. The Court will not prohibit testimony based relevant to state tort law and not preempted by the FDCA. Accordingly, the Court will allow Dr. Parisian to testify to the general nature of the FDA's approval and regulatory process, the FDA's general expectations with respect to testing and marketing of new products, and Woo Young's actions in that respect, to the extent supported by the record evidence.

Woo Young also asserts that Dr. Parisian should not be permitted to argue that there was actual promotion and marketing of the Accufuser for orthopedic use, when she has no evidence of this fact other than the distribution agreement described above. The Court will prohibit Dr. Parisian from testifying that Woo Young promoted the Accufuser for orthopedic use, assuming, as it appears, that she does not have personal knowledge of this fact. However, the Court will allow her to describe the source documents that she used to form her opinions and to offer opinions based on those documents.[20] The Court will consider objections to specific testimony about the source documents used by Dr. Parisian at trial.

Woo Young further argues that Dr. Parisian should not be allowed to testify as to causation. Block responds that Dr. Parisian will not testify as to causation or diagnosis. If Dr. Parisian in fact attempts to offer such testimony at trial, the Court will prohibit such

[20] *See, e.g.*, *Daubert*, 509 U.S. at 592 ("[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation"); *Sementilli v. Trinidad Corp.*, 155 F.3d 1130, 1134 (9th Cir. 1998) (holding that an expert may "base his or her opinions and inferences on facts and/or data perceived by or made known to the expert at or before the hearing" (internal quotation marks omitted)).

testimony at that time. Similarly, Woo Young argues that Dr. Parisian will testify in narrative form, but Block states that she will not do so.

Woo Young finally argues that Dr. Parisian does not have a sound methodology, but rather simply states various alleged facts and does not draw them together based on any expertise. However, the Court finds that Dr. Parisian's opinions are supported by a sufficiently reliable methodology. She has grounded her opinions in sources including Woo Young's internal documents, pertinent scientific literature, and publicly available documents, as well as her expertise. She also provided adequate descriptions for the bases for her opinions. The Court thus finds that her opinions are sufficiently supported to survive Woo Young's motion and that any challenges to these opinions can be adequately addressed through objections at trial, if appropriate, and though cross examination. *See Daubert*, 509 U.S. at 596.[21]

IV. MOTION TO EXCLUDE MARIA VARGAS AND LARRY STOKES

Finally, Woo Young moves to dismiss the expert opinions of Maria Vargas and Larry Stokes, who intend to provide expert opinions on Block's earning capacity and her projected future expenses. Woo Young argues that Vargas, a life care planner, bases her testimony on speculation, that Vargas cannot accurately predict what Block would have earned because she has no information about what Block ever earned, that Vargas provides no support for her estimates about the cost of surgeries, and that Vargas makes

[21] Woo Young also argues that Dr. Parisian should be prohibited from testifying regarding subject matter related to events occurring after Block's surgery. This issue has not been thoroughly briefed so the Court will not decide this issue at this time.

unsupported assumptions about Block's future needs. Because Stokes's report is based on Vargas's life care plan for Block, Woo Young argues that his report should also be excluded.[22]

The Court will deny Woo Young's motion and will permit Vargas and Stokes to testify. As a preliminary matter, according to Block, Vargas will not offer opinions on Block's loss of earnings and/or earning capacity. Instead, as a life care planner, Vargas will testify regarding the recommendations of medical providers regarding Block's care, resources available in the local community, the costs of those resources, and how treatments are provided. The Court finds that Vargas's opinions on these topics are properly supported, within Vargas's expertise of a life care planner, and would be helpful to the jury.

More specifically, Vargas will testify regarding Block's future medical needs. The Court finds that her opinions in this respect are properly based on the recommendations of Dr. Carl Basamania, one of the orthopedic surgeons who provided care to Block when she was injured. Vargas also based her opinions on the review of medical records, her interview and observation of Block, and her own research on Block's condition. The Court finds that Vargas therefore has adequate support for her opinions.

Because the Court has found that Vargas's opinions and testimony are admissible, Woo Young's challenges to Stokes's testimony also fail. The Court will therefore deny

[22] Woo Young has deposed neither Vargas nor Stokes.

Woo Young's motion to exclude the testimony of Vargas and Stokes but, as with all experts, will entertain any specific objections to their testimony at trial.

This case will be placed on the Court's next available trial calendar.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendant's Motion for Summary Judgment [Docket No. 245] is **GRANTED in part** and **DENIED in part:**

   a. Count 1 of Plaintiff's complaint is **DISMISSED**;

   b. The motion is otherwise **DENIED**.

2. Defendant's Motions to Exclude Expert Testimony and Reports [Docket Nos. 248, 251, 254, 257, 260] are **DENIED** as described above.

DATED: March 28, 2013
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge